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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/273, 164 03/19/99 ROBERTS

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EXAMINER

COOK, L

ART UNIT

PAPER NUMBER

1641

6

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/273,164

Applicant(s)

Roberts et al.

Examiner

Lisa V. Cook

Group Art Unit

1641



Responsive to communication(s) filed on Jun 28, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 835 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-14, 30-35, and 51-181 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-14, 30-35, and 51-181 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - A. Claims 1-14, and 30-34, are drawn to methods for detecting pregnancy in bovine animals, classified in class 436, subclass 65.
  - B. Claim 35 and 51 are drawn to an antibody composition and its corresponding hybridoma cell, classified in class 530, subclass 387.1 and class 435, subclass 326.
  - C. Claim 52 is drawn to a method of making an antibody, classified in class 435, subclass 6.
  - D. Claims 53 and 54 are drawn to methods of identifying a pregnancy associated glycoprotein (PAG) in an Eutherian animal, classified in class 435, subclass 344.1.
  - E. Claims 55 and 56, are drawn to the BoPAG2 polypeptide (Seq Id No:25), classified in class 530, subclass 300 or class 530, subclass 350.
  - F. Claims 57 and 58, are drawn to the BoPAG4 polypeptide (Seq Id No:27), classified in class 530, subclass 300 or class 530, subclass 350.
  - G. Claims 59 and 60, are drawn to the BoPAG5 polypeptide (Seq Id No:28), classified in class 530, subclass 300 or class 530, subclass 350.
  - H. Claims 61 and 62, are drawn to the BoPAG6 polypeptide (Seq Id No:29), classified in class 530, subclass 300 or class 530, subclass 350.

- I. Claims 63 and 64, are drawn to the BoPAG7 polypeptide (Seq Id No:30), classified in class 530, subclass 300 or class 530, subclass 350.
- J. Claims 65 and 66, are drawn to the BoPAG9 polypeptide (Seq Id No:32), classified in class 530, subclass 300 or class 530, subclass 350.
- K. Claims 67 and 68, are drawn to the BoPAG7v polypeptide (Seq Id No:40), classified in class 530, subclass 300 or class 530, subclass 350.
- L. Claims 69 and 70, are drawn to the BoPAG9v polypeptide (Seq Id No:42), classified in class 530, subclass 300 or class 530, subclass 350.
- M. Claims 71 and 72, are drawn to the BoPAG15 polypeptide (Seq Id No:44), classified in class 530, subclass 300 or class 530, subclass 350.
- N. Claims 73 and 74, are drawn to the BoPAG16 polypeptide (Seq Id No:46), classified in class 530, subclass 300 or class 530, subclass 350.
- O. Claims 75 and 76, are drawn to the BoPAG17 polypeptide (Seq Id No:48), classified in class 530, subclass 300 or class 530, subclass 350.
- P. Claims 77 and 78, are drawn to the BoPAG18 polypeptide (Seq Id No:50), classified in class 530, subclass 300 or class 530, subclass 350.
- Q. Claims 79 and 80, are drawn to the BoPAG19 polypeptide (Seq Id No:52), classified in class 530, subclass 300 or class 530, subclass 350.
- R. Claims 81 and 82, are drawn to the BoPAG20 polypeptide (Seq Id No:54), classified in class 530, subclass 300 or class 530, subclass 350.

- S. Claims 83 and 84, are drawn to the BoPAG21 polypeptide (Seq Id No:56), classified in class 530, subclass 300 or class 530, subclass 350.
- T. Claims 85-87, are drawn to a nucleic acid encoding BoPAG2 (Seq Id No:2 and Seq ID No:25), classified in class 536, subclass 23.1.
- U. Claims 88-90, are drawn to a nucleic acid encoding BoPAG4 (Seq Id No:4 and Seq ID No:27), classified in class 536, subclass 23.1.
- V. Claims 91-93, are drawn to a nucleic acid encoding BoPAG5 (Seq Id No:5 and Seq ID No:28), classified in class 536, subclass 23.1.
- W. Claims 94-96, are drawn to a nucleic acid encoding BoPAG6 (Seq Id No:6 and Seq ID No:29), classified in class 536, subclass 23.1.
- X. Claims 97-99, are drawn to a nucleic acid encoding BoPAG7 (Seq Id No:7 and Seq ID No:30), classified in class 536, subclass 23.1.
- Y. Claims 100-102, are drawn to a nucleic acid encoding BoPAG9 (Seq Id No:9 and Seq ID No:32), classified in class 536, subclass 23.1.
- Z. Claims 103-105, are drawn to a nucleic acid encoding BoPAG7v (Seq Id No:39 and Seq ID No:40), classified in class 536, subclass 23.1.
- AA. Claims 106-108, are drawn to a nucleic acid encoding BoPAG9v (Seq Id No:41 and Seq ID No:42), classified in class 536, subclass 23.1.
- BB. Claims 109-111, are drawn to a nucleic acid encoding BoPAG15 (Seq Id No:43 and Seq ID No:44), classified in class 536, subclass 23.1.

- CC. Claims 112-114, are drawn to a nucleic acid encoding BoPAG16 (Seq Id No:45 and Seq ID No:46), classified in class 536, subclass 23.1.
- DD. Claims 115-117, are drawn to a nucleic acid encoding BoPAG17 (Seq Id No:47 and Seq ID No:48), classified in class 536, subclass 23.1.
- EE. Claims 118-120, are drawn to a nucleic acid encoding BoPAG18 (Seq Id No:49 and Seq ID No:50), classified in class 536, subclass 23.1.
- FF. Claims 121-123, are drawn to a nucleic acid encoding BoPAG19 (Seq Id No:51 and Seq ID No:52), classified in class 536, subclass 23.1.
- GG. Claims 124-126, are drawn to a nucleic acid encoding BoPAG20 (Seq Id No:53 and Seq ID No:54), classified in class 536, subclass 23.1.
- HH. Claims 127-129, are drawn to a nucleic acid encoding BoPAG21 (Seq Id No:55 and Seq ID No:56), classified in class 536, subclass 23.1.
- II. Claims 130 and 131, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:9, classified in class 435, subclass 91.1.
- JJ. Claims 132 and 133, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:7, classified in class 435, subclass 91.1.
- KK. Claims 134 and 135, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:6, classified in class 435, subclass 91.1.

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- LL. Claims 136 and 137, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:5, classified in class 435, subclass 91.1.
- MM. Claims 138 and 139, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:4, classified in class 435, subclass 91.1.
- NN. Claims 140 and 141, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:2, classified in class 435, subclass 91.1.
- OO. Claims 142 and 143, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:39, classified in class 435, subclass 91.1.
- PP. Claims 144 and 145, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:41, classified in class 435, subclass 91.1.
- QQ. Claims 146 and 147, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:43, classified in class 435, subclass 91.1.
- RR. Claims 148 and 149, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:45, classified in class 435, subclass 91.1.

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- SS. Claims 150 and 151, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:47, classified in class 435, subclass 91.1.
- TT. Claims 152 and 153, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:49, classified in class 435, subclass 91.1.
- UU. Claims 154 and 155, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:51, classified in class 435, subclass 91.1.
- VV. Claims 156 and 157, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:53, classified in class 435, subclass 91.1.
- WW. Claims 158 and 159, are drawn to an oligonucleotide comprising at least 15 consecutive bases of Seq Id No:55, classified in class 435, subclass 91.1.
- XX. Claims 160-170, are drawn to an antibody kit, classified in class 422, subclass 61.
- YY. Claims 171-181, are drawn to a method of detecting pregnancy in a non-bovine Eutherian animal, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

I. Inventions E - S are drawn to a plurality of disclosed patentably distinct inventions (polypeptides comprising materially different amino acid sequences as evidence by separate SEQ ID Numbers). The separate polypeptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers and having different binding epitopes for unique diverse antibodies as defined in the disclosure (See page 34, Antigen compositions). **Therefore, each disclosed patentably distinct polypeptide is considered a separate invention.**

II. Inventions T-HH are drawn to a plurality of disclosed patentably distinct inventions (nucleic acid compositions comprising materially different amino acid sequences as evidence by separate SEQ ID Numbers). The separate nucleic acid compositions bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers. **Therefore, each disclosed patentably distinct nucleic acid composition is considered a separate invention.**

III. Inventions II-WW are drawn to a plurality of disclosed patentably distinct inventions (oligonucleotides comprising materially different amino acid sequences as evidence by separate SEQ ID Numbers). The separate oligonucleotides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers and having different binding epitopes for unique diverse antibodies as defined in the disclosure (See page 34, Antigen compositions). **Therefore, each disclosed patentably distinct oligonucleotide is considered a separate invention.**

IV. Inventions (E-S), (T-H), and (II-WW) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventive products comprise different compositions with separate sequences requirements. Inventions F-T are directed to polypeptides with certain seq. Id nos. while, inventions U-II are directed to nucleic acids encoding the polypeptides. The inventions directed to the oligonucleotide products is distinguishable from both the nucleic acids and polypeptides because the oligonucleotides have different structural requirements that are not identical to the polypeptides or nucleic acids that are claimed. Specifically the oligonucleotides comprise at least 15 consecutive bases of the polypeptide sequences or complements thereof. These distinctions render the polypeptides, nucleic acids, and oligonucleotides patentably independent possibly having different modes of operation, different functions, or different effects because they are materially different products.

It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where by the search for one would fully encompass the search for the others. Because these inventions are distinct for the reasons given above and the search required for Inventions (E-S), Inventions (T-H) or Inventions (II-WW) are not mutually inclusive (i.e. the search for one invention is not required for the other inventions) restriction for examination purposes as indicated is proper.

V. Inventions (B, XX) and (E-WW) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of inventions B and (E-WW) are patently distinct. Invention B is directed to an antibody and invention XX is drawn to an antibody kit. An antibody is a molecule that defends the body against bacteria, viruses, or other foreign bodies (see The mosby medical encyclopedia, revised edition, copyright 1985, page 48, 1<sup>st</sup> column). This limitation is not required for the polypeptide, nucleic acid, or oligonucleotide products of inventions E-WW. Therefore the antibody product and a kit employing an antibody are required to exhibit a different mode of operation, function, and effect. And is patentably distinct from the other inventions.

VI. The method inventions A, C, D, and YY are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. Invention A is directed to pregnancy detection in bovine animals, Invention C is a method of making an antibody, Invention D is drawn to pregnancy detection in an Eutherian animal, and Invention YY is drawn to pregnancy detection in a non-bovine Eutherian animal. Further, because all the methods have different method steps, employing different reagents, they are independent and separate methods/inventions.

VII. Inventions (A, C, D, YY) and XX are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the kit/apparatus of invention XX can be utilized in any of the materially different processes of inventions A, C, D, or YY.

VIII. Inventions C and B are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed immunizes an animal with a BoPAG preparation to generate an antibody-secreting cell. This method of making is used to produce various significantly different products. Such a method can generate several materially different products with separate seq. Id. nos., like the ones recited in claim 52 or the specification (i.e. see pages 45-50).

IX. Inventions (A, C, D, YY) and (E-WW) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the different inventions of (A, C, D, YY) are method to detect pregnancy and the inventions of (E-W) are products.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook  
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Art Unit 1641  
CM1-7D16



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